

Reference number
3491-A

SPECIALTY GUIDELINE MANAGEMENT

AYVAKIT (avapritinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Gastrointestinal Stromal Tumor (GIST)

Ayvakit is indicated for the treatment of adults with unresectable or metastatic GIST harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: PDGFRA exon 18 mutation testing (e.g., polymerase chain reaction [PCR]-based assay, next-generation sequencing [NGS]-based assay) results.

III. CRITERIA FOR INITIAL APPROVAL

Gastrointestinal Stromal Tumor (GIST)

Authorization of 12 months may be granted for treatment of gastrointestinal stromal tumor (GIST) when all of the following criteria are met:

1. The member has unresectable or metastatic disease.
2. The disease harbors a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for gastrointestinal stromal tumor (GIST) who have not experienced disease progression or unacceptable toxicity.

V. REFERENCES

1. Ayvakit [package insert]. Cambridge, MA: Blueprint Medicines Corporation.; January 2020.